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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/460,715	06/02/1995	MICHAEL MACH	5552.0738-02	5690

22852 7590 09/19/2002

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EXAMINER

WORTMAN, DONNA C

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 09/19/2002

32

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/460,715

Applicant(s)

MACH ET AL.

Examiner

Donna C. Wortman, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,8,19,21,37,39 and 41-61 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19,21,37,39 and 41-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 7,8,19,21,37,39 and 41-61 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 07/313,553.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's second submission after final filed on July 10, 2002, has been entered.

Claims 19, 21, 37 and 39 were amended, claims 20, 22-36, 38, and 40 were canceled, and claims 41-61 were added in Paper No. 31 submitted July 10, 2002. Claims 7 and 8 remain pending and withdrawn from consideration as drawn to a non-elected invention. Claims 19, 21, 37, 39 and 41-61 are under examination.

Claims 19, 21, 54, 41-43, 48, 49, 55-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 19, 21, 54, 41, 41-43, 48, 49, 55-57 are drawn to expression vectors that encode HCMV pp28 or antigenic portions of HCMV pp28 and to transformed cells that express HCMV pp28 or antigenic portions of HCMV pp28. The specification describes expression vectors encoding portions of HCMV pp28 protein from strain AD169 in the form of fusion proteins, but does not appear to describe an expression vector that encodes the entire HCMV pp28 or transformed prokaryotic and eukaryotic cells that express the entire HCMV pp28. This matter might be resolved if Applicant were to point to the portion of the specification that describes the expression vectors and transformed cells as now claimed.

Claims 44, 53, and 61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 44, 53, and 61 recite "comprises 270 bp of HCMV pp28." While the intended limitations of the cited phrase are rather unclear as discussed below, and while a particular 270 bp segment of HCMV Ad169 pp28 is disclosed on pages 2-3 of the instant specification, no support in the as-filed specification could be located for claiming, broadly, any and all HCMV pp28 segments that are 270 bp in size.

Claims 37, 39, 45, 46, 47, 50, 51, 52, 58, 59, and 60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated 0.5 kB Kpn/Sma DNA fragment encoding an antigenic portion of HCMV strain Ad 169 pp28 that elicits antibodies that immunologically bind to HCMV, and for an isolated 0.5 kB Sma/KpnI DNA fragment encoding an antigenic portion of HCMV strain Ad 169 pp28, and for an isolated 1.0 kB Sma/Sma DNA fragment encoding an antigenic portion of HCMV strain Ad 169, and for vectors and cells transformed with those DNA fragments, does not reasonably provide enablement for an isolated 0.5 kB Kpn/Sma fragment encoding an antigenic portion of HCMV, or for an isolated 0.5 kB Sma/KpnI DNA fragment encoding an antigenic portion of HCMV, or for an isolated 1.0 kB Sma/Sma fragment encoding an antigenic portion of HCMV from other HCMV strains. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention

commensurate in scope with these claims. The specification does not provide guidance for determining the appropriate restriction fragments nor provide any other guidance for locating the corresponding region in other HCMV strains.

Applicant has argued, in Paper No. 31, that the specification provides information, at page 2-3, and that the "same methods" can and have been used to obtain prokaryotic expression vectors encoding HCMV pp28 in strains other than Ad169, and has cited Pande 1991, of record, and Pande 1988, attached, as evidence that the "same techniques" disclosed in the specification enabled Pande et al. to obtain vectors encoding HCMV pp28 from HCMV Towne strain.

Applicant's arguments have been considered but not found persuasive. Pande et al. used HCMV Towne strain, which has a restriction map that is different from HCMV Ad169's restriction map; constructed a Towne strain genomic library different from the library of Fleckenstein disclosed by Applicant; and used a monoclonal antibody, Mab-48, different from the monoclonal antibody, P2G11, used by Applicant to recognize expressed pp28. Applicant does not disclose the techniques used by Pande and does not provide guidance as to making KpnI/SmaI, SmaI/KpnI, or SmaI/SmaI fragments as now claimed, for additional HCMV strains.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37, 39, 45, 50 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 37 is indefinite because it recites "pp28" without any indication of the origin of the protein. Amending the claim to read "HCMV pp28" would overcome this rejection.

Claims 39, 45, 50, and 58 are indefinite because claim 39 recites "1.0 kB Smal/Smal fragment" while claims 45, 50, and 58 recite "1.0 kB Smal fragment." It is not clear whether the cited material is intended to represent the same fragment. If so, it is recommended that consistent terminology be used throughout the claims in order to prevent confusion. If not, clarification as to the intended difference is needed.

Claims 44, 53, and 61 are indefinite in reciting "comprises 270 bp of HCMV pp28." It is not clear whether "270 bp" is intended to be the same 270 bp as disclosed on pages 2-3 of the specification, or whether Applicant intends to claim any 270 bp of HCMV pp28. The metes and bounds of the claims are unclear.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:30-5:00 and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'Donna C. Wortman', with a long horizontal line extending to the right.

Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw
September 18, 2002